

TOYA108.013APC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: HIGUCHI et al.

Application No.: 10/572,404

Filing Date: March 16, 2006

For: DRUG AND FOOD OR DRINK FOR
IMPROVING HYPERGLYCEMIA

Art Unit: 1623

Examiner:

BLAND, LAYLA D

Attorney DOCKET No.:

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DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents

P.O.Box 1450

Alexandria, VA 22313-1450

Dear Sir:

I declare as follows:

1. I am employee of Morinaga Milk Industry Co., Ltd. located at 33-1, Shiba 5-chome, Minato-ku, Tokyo, Japan, which is engaged in the business of production and sale of milk, and other foods.

2. I am one of co-inventors of the above-identified patent application.

3. <Regarding Tissue of Aloe Leaf>

The aloe leaf can be divided largely into three (3) portions, as follows. See the referential patent document, US Patent No. 4,735,935, especially Fig. 1 thereof.

1. Inner clear gel.

2. Yellow liquid which is present between the rind and the inner clear gel (the dry matter is in brownish-red color).

3. Rind (Cortex).

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A description of each of the above-mentioned Portions will be made below.

(i) The above-mentioned Portion 1 and 2 are present in the aloe leaf in the separate state. See US Patent No. 4,735,935, specifically Column 1 thereof.

Further, please see attached color photograph, in which the left side is the above-mentioned Portion 1, and the right side is the above-mentioned Portion 2.

(ii) The yellow liquid of the above-mentioned Portion 2 is oozed or drained from the cut-away surface when the aloe leaf is cut-away. See the right side in the attached color photograph.

(iii) Water contained in the above-mentioned Portion 1 does not flow out from the cut-away surface by simply cutting-away the aloe leaf, because water is retained in the gel. See the right side of the attached color photograph.

(iv) The dry matter of the yellow liquid of the above-mentioned Portion 2 is called "Aloes", which is known as in brownish-red color and bitter in taste. See the US Patent No. 4,735,935, specifically Column 1 thereof.

(v) In the field of this art, the above-mentioned Portion 1 is classified as "Aloe vera", and the dry matter of the above-mentioned Portion 2 is classified as "Aloes."

4. <Regarding the drained liquid described in Ajabnoor>

It is apparent from the second sentence of the "Introduction" of Ajabnoor that the "drained liquid" called in Ajabnoor is the above-mentioned Portion 2 of the aloe leaf.

It is described: "Aloes (English) or Saber (Arabic) is the dried brownish mass (crystalline or glossy) of the drained liquid from the cut leaves of various species of Aloe, and is very bitter in taste."

However, this "drained liquid" does not contain 9,19-cyclolanostan-3-ol specified by the present invention as indicated in

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the 132 Declaration submitted by the applicant on April 30, 2009. Thus, this compound is not contained in the Aloes (dry matter) of the drained liquid, nor in the bitter principle in the Aloes.

As a conclusion, as it was stated in the response filed on April 30, 2009, it is apparent that the drained liquid of Ajabnoor is different from the extract specified by the present invention in respect of the concentration of 9,19-cyclolanostan-3-ol.

As it is described in the specification of the present application, page 17, paragraph 4, the above-mentioned compound is the component contained in the clear gel of the above-mentioned Portion 1 of the aloe leaf.

5. <The Relation between the Two 132 Declarations>

The 132 Declaration submitted by the applicant on April 30, 2009 indicates the concentration of 9,19-cyclolanostan-3-ol in the drained liquid of Ajabnoor. In other words, the Declaration of April 30, 2009 indicates the concentration of the compound in the yellow liquid of the above-mentioned Portion 2 of the aloe leaf.

On the other hand, the 132 Declaration submitted by the applicant on May 15, 2008 indicates the concentration of 9,19-cyclolanostan-3-ol in the Aloe vera juice described in Yongchaiyudha.

The Aloe vera juice described in Yongchaiyudha is obtained by squeezing aloe gel, as described in the paragraph under the sub-heading of *Sample of Yongchaiyudha*.

That is, this previous 132 Declaration indicates the concentration of 9,19-cyclolanostan-3-ol in the juice obtained by squeezing the clear gel of the above-mentioned Portion 1 of the aloe leaf.

As explained above, the sample "drained liquid" in the 132 Declaration submitted on April 30, 2009 and the sample "Aloe vera juice" in the 132 Declaration submitted on May 15, 2008 were obtained from different tissues of the aloe leaf. Hence, the result indicates different content of 9,19-cyclolanostan-3-ol, and this is technically reasonable.

6. I further declare that all statements made herein of our own knowledge

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are true, and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By: Miyuki Tanaka
Miyuki Tanaka

Date: September 29, 2009